NATIONAL FISHERIES INSTITUTE

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Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Rm. #1061
Rockville, MD 20852

Re: Docket No. 99N-3089

Dear Sir or Madam:

I am writing to provide comment on FDA's "Draft Affirmative Agenda for International Activities." The National Fisheries Institute (NFI) is the nation's largest non-profit trade association representing the diverse fish and seafood industry. NFI members include producers, processors, wholesalers, distributors, brokers, importers, exporters, aquaculturists, retailers, foodservice operators, broadline distributors, and members of allied supportive industries. NFI acts to ensure an ample, sustainable, and safe seafood supply for consumers and strengthens members' ability to succeed in the worldwide seafood marketplace.

In 1998, 3.6 billion pounds of edible fishery products were imported into the U.S. and 1.7 billion pounds were exported to other countries. Given the global scope of the fish and seafood industry, NFI members are substantially impacted by and interested in FDA's international objectives. Overall, NFI supports FDA's international activities and believes that U.S. consumers benefit from the increased level of food safety assurance they yield. Our comments on the specific activities follow.

I. Regulatory Activities

NFI agrees that FDA should enhance the effectiveness of its import monitoring programs. However, FDA's plan to increase the surveillance of imported foods to ensure they meet U.S. food safety standards will not necessarily increase the program's "effectiveness" substantially. An effective import-monitoring program should provide adequate assurance that imported food is safe without causing undue impediment to trade. Unfortunately, the existing FDA laboratory structure and lack of import compliance officers will limit FDA's ability to increase surveillance sampling significantly. Moreover, food importers already often endure long delays in the release of products held for sampling due to the aforementioned facility and personnel limitations. Attempts to increase the amount of sampling without first addressing these limitations will only create more frequent and lengthy delays.

NFI believes that to achieve expanded surveillance effectively, FDA must review and adjust, as needed, its allocation of import inspection personnel (i.e. the number of and ratio between import investigators and compliance officers) and improve its laboratory capabilities. FDA should consider the possibility of outsourcing some of the laboratory work as one option for enhancing testing capacity.

NFI believes FDA can best attain its goal of creating a more effective import inspection program through the establishment of enforceable inspection equivalency memorandums with key trading partners. These agreements would allow the agency to leverage its inspection resources with those of nations that can demonstrate equivalent inspection programs. The FDA could then target its import surveillance efforts on a smaller number of countries and dedicate more time to helping non-MOU countries to improve their inspection capabilities through compliance visits.

Moreover, foreign inspections can help improve the compliance rate of nations that export food to the U.S. and help FDA determine where it can relax or conversely intensify its surveillance efforts. The visits will also enable exporting countries to adjust their inspection programs to compliance with U.S. standards. FDA should publish a summary of these country inspections. U.S. importers could use this information to assess their overseas business relationships and work with suppliers to make improvements when needed.

NFI notes that FDA wishes to promote foreign compliance with U.S. labeling requirements. In carrying out his compliance goal, FDA should ensure that its label requirements are harmonized internationally to avoid unnecessary regulatory discrepancies such as those created by the introduction of mandatory nutrition labeling (e.g. with Mexico and Canada).

II. Strengthen CFSAN Participation in Codex

NFI agrees that FDA must continue to strengthen its role in pertinent Codex Committees. The standards and guidelines established through the Codex mechanism increasingly provide the basis for international trade negotiations and treaties. The food industry must also be adequately engaged in Codex discussions and FDA should help facilitate frequent interaction with its constituency to assure that emerging standards are practicable for the industry to implement.

FDA is recognized as a leading food safety authority and must strive to maintain that reputation through aggressive involvement in the various Codex Committees, NAFTA and FTAA Technical Committee meetings and other international activities. FDA should take an active role in the facilitation and assessment of scientific research to develop harmonized science-based standards and methods of analysis and verification.

III Development, Maintenance and Dissemination of CFSAN's Science Base

The NFI applauds CFSAN's intention to strengthen its scientific and technical collaboration with appropriate foreign governments and international organizations in order to enhance our ability to make risk management decisions based on sound science.

IV Equivalence Evaluations, Food Safety Needs Assessments and Food Safety Technical Cooperation and Assistance

NFI requests that FDA establish equivalence criteria for food inspection systems. The criteria are of urgent need due to the increasing diversity of inspection programs and food safety standards worldwide. U.S. authorities and their negotiating partners must recognize that an "equivalent" inspection system is not necessarily an "identical" system. The criteria must be very clear and concise concerning what constitutes equivalence but must, at the same time, avoid legal gridlock over terminology.

The import compliance component of the Seafood HACCP regulation has received criticism for delegating too much of the responsibility for foreign processor compliance on U.S. seafood importers. While fish and seafood importers have responded to the sizable task of verifying supplier HACCP programs, FDA continues to receive undue criticism that it is not sufficiently ensuring the safety of imported foods. As stated previously, NFI believes that the establishment of inspection MOUs with multiple trading partners, particularly concerning HACCP seafood inspection, will leverage resources and provide greater consumer confidence in imported food safety.

V International Trade Agreements and Other Trade-Related Activities

FDA must maintain a high profile in all emerging discussions regarding food standards and guidelines at an international level. It must also ensure that sufficient input is sought from the food industry in the establishment of measures under the World Trade Organization's SPS Committee. FDA must maintain its ability to protect the integrity of a science-based WTO and defend against barriers to trade that are not based on sound science.

The NFI appreciates this opportunity to comment on CFSAN's International Priorities for 2000-2002. We look forward to working with the FDA in these efforts in the interest of ensuring harmonized food safety standards and inspection systems.

Sincerely,

Robert L. Collette (dlh)

Robert L. Collette
Vice President of Science & Technology